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REMARKET NOTIFICATION

510(k) SUMMARY

(As Required By 21 CFR 807.92)

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is: K110074 Date: 2012.02.29 revised

1. Submitter:

Health & Life Co., Ltd.
9F, No.186, Jian Yi Road, Chung-Ho District, New Taipei City, Taiwan, R.O.C.
TEL: +886-2-8227-1300
FAX: +886-2-8227-1301

Contact person: Sarah Su/ Regulatory Affairs Dept.
E-mail: sarah.su@hlmt.com.tw
Tel: 886-2-8227-1300 ext.1201
Fax: 886-2-8227-1301

2. Name of the Device:

Proprietary Name: HL568 Self-Monitoring Blood Glucose System
Common Name: Blood Glucose Monitoring System
Classification Name: Glucose Test System
Classification:
21 CFR 862.1345 Glucose Test System, Class II
21 CFR 862.1660 Quality Control Material, Class I
Product Code: NBW, CGA, JJX
Panel: Clinical Chemistry (75)

3. Information for the 510(k) Cleared Device (Predicate Device):

ONE TOUCH ULTRA blood Glucose Monitoring System

a. Device name: ONE TOUCH ULTRA blood Glucose Monitoring System
b. Classification Name: Glucose Test System
c. Common Name: Glucose Test System
d. Device Classification : Class II ; Class I
e. Regulatory Information: 21 CFR 862.1345 ; 21 CFR 862.1660
f. Panel: Clinical Chemical (75)
g. Product code: NBW
h. 510(K) Number: K062195

4. Device Description:

4.1 Blood Glucose Concentration Measurement

The HL568 Self-Monitoring Blood Glucose System is comprised of the HL568 Blood Glucose Meter, HL568 Blood Glucose Test Strip, HL568 Control Solution (2 levels), a lancing device and lancets. All the measured values can be read out in one LCD panel, battery operated and the blood glucose meter is portable. The Subject Device is self-test IVD medical device which is intended for quantitative measurement of blood glucose (β-D-glucose) levels from fresh capillary whole blood obtained from the fingertip and used outside the body only (*in vitro* diagnostic use). It is intended for over-the-counter, home use by single patient to measure the glucose concentration for aiding diabetes management.

4.2 Test Principle

The test principle based on the electrochemical biosensor technology using glucose oxidase method. Each test strip reacts with glucose in the blood sample to produce a current proportional to the blood glucose level. This reaction is measured by the meter and displayed as the blood glucose result.

4.3 USB data transmission Function

The Subject Device is designed to have USB computer interface to allow users make use of their storage memory data more personalized. Users can transfer the readings of their blood glucose meters to the connected personal computer (PC) via USB cable to save and manage their personal data. Once the software program included in the accompany software CD is installed, users can manage their measurement data personally, such as transferring data, deleting data, viewing the readings on a chart and restoring data. (Please refer to Attachment A-4-1, A-4-7(SDS, SRS), A-4-11(Functionality validation report) and A-5-5(D-FMEA) for more detail information)

4.4 Audio function

Subject Device, HL568 Blood Glucose Meter is featured with an audio function for use to easily and efficiently perform the glucose testing. It provides an auditory aid for the users to know the measured result by hearing and to use the device step by step. When, or symbol appears on the screen, it indicates the audio function is on with volume from high to low. User can use this optional feature at their discretion. (Please refer to Attachment A-4-1, A-4-7 (SDS, SRS), A-4-11 (Functionality validation report) and A-5-5(D-FMEA) for more detail information)

4.5 Special condition for use statement(s)

HL568 Blood Glucose Test Strip and HL568 Control Solution are designed to be used only with the HL568 Blood Glucose Meter. Also, the proposed device is not intended for use in the alternative site testing other than the fingertip.

5. Intended Use

HL568 Self-Monitoring Blood Glucose (SMBG) System is self-test medical device and intended for single patient home-use to monitor the blood glucose (β-D-glucose) levels in quantitative measurement from fresh capillary whole blood obtained from the finger tip. It is intended for use outside the body (in vitro diagnostic use) by diabetics at home to measure the glucose concentration for aiding diabetes management. It is not intended for the diagnosis of or screening for diabetes mellitus.

HL568 Self-Monitoring Blood Glucose (SMBG) System is intended to be used by a single person and should not be shared and it is also not intended for use on neonates and should be used with HL568 Blood glucose test strip and HL568 Control Solution.

HL568 Blood glucose test strips are for use with the HL568 Blood glucose meter to quantitatively measure glucose in fresh capillary whole blood samples drawn from the fingertip.

HL568 Control Solutions are for use with the HL568 Blood glucose meter and HL568 Blood glucose test strips to check that the meter and test strips are working together properly and that the test is performing correctly.

The device is capable of transferring the storage data to the connected personal computer (PC) via USB cable. In addition, HL568 Self-Monitoring Blood Glucose System is featured with audio function; it could help the user to know the measured result by hearing but is not

intended for visually impaired users.

6. Comparison of Subject Devices and predicate device:

Technological Characteristics Comparison Table of HL568 Self-Monitoring Blood Glucose System and ONE TOUCH ULTRA blood Glucose Monitoring System (K062195)

Similarities		
Item	***Subject Device*** HL568 SMBG System	***Predicate Device*** OneTouch Ultra Blood Glucose Monitoring System
Detection method	Amperometry: current is generated by oxidation of reduced mediator	same
Enzyme	Glucose Oxidase	same
Mediator	ferricyanide	same
Open Stability	3 months	same
Sample Type	Capillary whole blood	same
Calibration	Plasma equivalence	same
Test range	20 - 600 mg/dL	same
Coding Method	Coding by button	same
Altitude limit	10,335 feet	10,000 feet
Sample volume	> 1μL	Minimum 1μL
Hematocrit Range	30 - 55%	same
Test time	5 seconds	same
Differences		
Item	***Subject Device*** HL568 SMBG System	***Predicate Device*** OneTouch Ultra Blood Glucose Monitoring System
Operating temperature Range	50~104°F/10 - 40° C	43~111°F/6~44°C
Power	3V Alkaline battery (AAA X 2)	3V Li battery (CR2032)
Audio function	Voice aiding	No
Memory capability	500 tests	150 tests
Data transmission	USB interface	No
Battery life	500 tests (audio function on) 1000 tests	1000 tests

	(audio function off)	
Operating Humidity	R.H. ≤ 80%	R.H.:10% to 90%
Day average	7, 14, 28, 60, 90-day average	14, 30-day average
Meter Dimension L x W x H	3.90" x 1.96 x 0.87"	3.12" x 2.25' x 0.85"
Meter Weight	1.94 ounces (without batteries)	1.5 ounces with battery

7. Discussion of Clinical Tests Performed:

HL568 Self-Monitoring Blood Glucose System (Subject Device) is compliant to the standard of ISO 15197-2003: In vitro diagnostic test systems - Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus. All the relevant activities were performed by designate individual(s) and the results demonstrated that the predetermined acceptance criteria were fully met.

8. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

The subject device was tested to evaluate its safety and effectiveness, including the followings:

a. 15197:2003 In vitro diagnostic test systems - Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus
b. IEC 60601-1:1988 + A1:1991 + A2:1995 Medical electrical equipment - Part 1: General requirements for safety
c. IEC 60601-1-2:2007 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performence - Collateral standard: Electromagnetic compatibility - Requirements and tests
d. CLSI/NCCLS EP05-A2: Evaluation of Precision Performance of Quantitative Measurement Methods
e. CLSI EP06-A: Evaluation of the Linearity of Quantitative Measurement.
f. CLSI EP07-A2: Interference Testing in Clinical Chemistry
g. CLSI/NCCLS EP09-A2: Method Comparison and Bias Estimation Using Patient Samples
h. FDA Guidance: Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices , May 11, 2005
i. FDA Guidance: Total Product Cycle Life for Portable Invasive Blood Glucose Monitoring System, October 24, 2006

9. Conclusions:

The subject device was tested and fulfilled the requirements from those standards mentioned above, and it's concluded that the subject device is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

10903 New Hampshire Avenue
Silver Spring, MD 20993

Health & Life Co., Ltd.
c/o Ms. Sarah Su
9F, No. 186, Jian Yi Road
Chung-Ho City, Taipei
China (Taiwan) 235

Re: k110074
Trade Name: HL568 Self-Monitoring Blood Glucose System
Regulation Number: 21 CFR §862.1345
Regulation Name: Glucose Test System
Regulatory Class: Class II
Product Codes: NBW, CGA, JJX
Dated: May 22, 2012
Received: May 25, 2012

MAY 25 2012

Dear Ms. Su:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance...

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm

Sincerely yours,

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K110074

Device Name:

HL568 Self-Monitoring Blood Glucose System

Indications for Use:

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Prescription Use _____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use __V___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K110074